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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/517,120 | 12/02/2004 | Ettore Bergamini | 833-131 US | 3135 |
| 26817 | 7590 | 01/25/2007 | | |
| MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A. 29 THANET ROAD, SUITE 201 PRINCETON, NJ 08540 | | | EXAMINER HANDY, NIKKI R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/25/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 10/517,120 | Applicant(s) BERGAMINI ET AL. | |
| | Examiner Nikki Handy | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/2/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 provides for the use of dolichol for the preparation of cosmetic and dermatological compositions designed to prevent acute and chronic skin damage caused by exposure to sunlight, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Toshiyuki (JPO 61293905).

Toshiyuki teaches a skin cosmetic for beautifying the body which provides for improved touch, keeping the skin healthy, developing and supplying a preventive effect on skin aging and beautifying effect when used, which contains dolichol. See Abstract, the Purpose. Dolichol was mixed with a suitable excipient which is purified water in the amount of 61.5 parts. See page 3, right column, line 11. The cosmetic contains 0.01-3wt% dolichol based on the total amounts of prescription of cosmetic obtained from swine liver by extraction, etc. The cosmetic promotes skin functions, prevents wrinkles on the skin, makes the skin fine and wet, has improved beautifying effects, improving effects on chapped skin and keratin and accelerating effect on turnover speed. See Abstract, the Constitution. The

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Toshiyuki (JPO 62148415).

Toshiyuki teaches a hair tonic, containing 0.005-3% dolichol that is capable of exhibiting remarkably good hair growth promoting effect by applying to

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human or animal skin and stable even in preservation for a long period. The hair tonic is formulated into a dosage form, e.g., hair tonic, hair lotion, hair cream, etc., according to a conventional method. The hair lotion is in liquid form which can be manufactured into a spray. Such dosage forms inherently contain excipients and/or additives.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toshiyuki (JPO 61293905) as applied to claims 1-3, 7 and 9 above, and in view of Dahle (US Application No. 2002/0039591 A1).

The applicant claims cosmetic and dermatological compositions containing dolichol mixed with suitable excipients and/or additives.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Toshiyuki teaches a skin cosmetic for beautifying the body which provides for improved touch, keeping the skin healthy, developed and supplying a preventive effect on skin aging and beautifying effect when used, which contains dolichol. See Abstract, the Purpose. Dolichol was mixed with a suitable excipient which is purified water in the amount of 61.5 parts. See page 3, right

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column, line 11. The cosmetic contains 0.01-3wt% based on the total amounts of prescription of cosmetic of dolichol obtained from swine liver by extraction, etc.

The cosmetic promotes skin functions, "prevents wrinkles on the skin", makes the skin fine and wet, has improved beautifying effects, improving effects on chapped skin and keratin and accelerating effect on turnover speed. See Abstract, the Constitution.

Dahle teaches novel combinations of mineral oil, vegetable shortening, "Vitamin E", purified water and other ingredients to form useful therapeutic, "dermatological", pharmaceutical, medical or "cosmetic compositions" for treatment of skin maladies and disorders. See Abstract. The composition can be embodied in creams, lotions, oils, sprays and other typical dosage forms for direct application to the skin. See page 1, paragraph 2. The most preferred mode of administration for treating the skin disorders is topical. See page 1, paragraph 13. In addition to these and other vehicles, it shall be understood that the therapeutic, dermatological, pharmaceutical, medical, and/or cosmetic compositions may include other ingredients to improve or eradicate analgesics, anti-fungal agents, antiviral agents, antibiotic agents, hair conditioners, hair treatments, "anti-aging agents", "anti-wrinkle agents", antihistamine agents, disinfectants, skin lightning agents, etc. See page 1, paragraph 17.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Toshiyuki does not teach an invention of mineral oil, vegetable shortening, "Vitamin E", purified water and other ingredients to form useful therapeutic,

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dermatological, pharmaceutical, medical or cosmetic compositions for treatment of skin maladies and disorders. He also does not teach the therapeutic, dermatological, pharmaceutical, medical, and/or cosmetic compositions that may include other ingredients to improve or eradicate analgesics, anti-fungal agents, antiviral agents, antibiotic agents, hair conditioners, hair treatments, anti-aging agents, anti-wrinkle agents, antihistamine agents, disinfectants, skin lightning agents, etc. It is for this reason that Dahle is joined. Dahle teaches a composition of mineral oil, vegetable shortening, "Vitamin E", purified water and other ingredients to form useful therapeutic, dermatological, pharmaceutical, medical or cosmetic compositions for treatment of skin maladies and disorders. See Abstract. The composition can be embodied in creams, lotions, oils, sprays and other typical dosage forms for direct application to the skin. See page 1, paragraph 2. The most preferred mode of administration for treating the skin disorders is topical. See page 1, paragraph 13. In addition to these and other vehicles, it shall be understood that the therapeutic, dermatological, pharmaceutical, medical, and/or cosmetic compositions may include other ingredients to improve or eradicate analgesics, anti-fungal agents, antiviral agents, antibiotic agents, hair conditioners, hair treatments, "anti-aging agents", "anti-wrinkle agents", antihistamine agents, disinfectants, skin lightning agents, etc. See page 1, paragraph 17.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

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It would have been obvious to one having ordinary skill in the art to modify the invention of Kaufman to include vitamin E. One would have been motivated to do add an additional ingredient, such as, vitamin E, to help retard aging.

Objection to the claims

Claim 8 is objected to because the prior art does not teach or suggest an instant composition containing carbon dioxide. Furthermore there is no combination to combine the ingredients with carbon dioxide.

Telephonic Inquiry


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki Handy whose telephone number is (571) 272-9923. The examiner can normally be reached on Monday-Friday 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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